UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THERESA ELDREDGE,	:	
PLAINTIFF	:	
	:	**CIVIL ACTION NO.**
vs.	:	
	:	
XANODYNE PHARMACEUTICALS, INC.,	:	
PROBST DISTRIBUTION, INC. f/k/a	:	**COMPLAINT AND CLAIM FOR**
QUALITEST PHARMACEUTICALS, INC.,	:	**JURY TRIAL**
VINTAGE PHARMACEUTICALS, LLC,	:	
GENERICS BIDCO I, LLC, d/b/a	:	
QUALITEST PHARMACEUTICALS,	:	
COVIDIEN, INC., COVIDIEN, PLC and	:	
MALLINCKRODT, INC.,	:	
	:	
DEFENDANTS.	:	

Plaintiff, Theresa Eldredge by her attorneys, MacDonald Rothweiler Eisenberg LLP**,** on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs claims occurred, in part, in the

Eastern District of Pennsylvania.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff, THERESA ELDRIDGE, who was prescribed, purchased and correctly used DARVOCET, also known generically as Propoxyphene Napsylate and Acetaminophen (hereinafter "DARVOCET").

5. Defendants, Xanodyne Pharmaceuticals, Inc., Probst Distribution, Inc. f/k/a Qualitest Pharmaceuticals, Inc., Vintage Pharmaceuticals, LLC, Generics Bidco I, LLC, d/b/a Qualitest Pharmaceuticals, Covidien, plc, Covidien, Inc., and Mallinckrodt, Inc. (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed DARVOCET for use as a prescription pain management medication.

6. Defendants concealed their knowledge of DARVOCET's defects from Plaintiff, the Food and Drug Administration (hereinafter referred to as "FDA"), the public in general and the medical community specifically.

7. When warning of safety and risks of DARVOCET, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, to Plaintiff and the public in general, that DARVOCET had been tested and was found to be safe and/or effective for its indicated use.

8. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase DARVOCET for use as a prescription pain management medication, all of

which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning DARVOCET's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, during clinical trials.

10. As a result of the defective nature of DARVOCET, those persons who use and/or used and relied on DARVOCET have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff herein has sustained certain of the above health consequences due to her use of DARVOCET.

12. Defendants concealed their knowledge of the defects in their product from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory damages as a result of her use of DARVOCET, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

THE PARTIES

14. Plaintiff, THERESA ELDREDGE, is a natural person and is a citizen of the Commonwealth of Pennsylvania.

15. Prior to October/November 2008, plaintiff, THERESA ELDREDGE, did not have a pre existing cardiac history and had never suffered a cardiac arrhythmia.

16. Plaintiff, THERESA ELDREDGE, was prescribed DARVOCET for pain management in or about October/November 2008.

17. As result of using Defendants's drug DARVOCET, Plaintiff THERESA ELDREDGE, was caused to suffer cardiovascular injuries and cardiac arrhythmias, including but limited to ventricular tachycardia and signs and symptoms of Postural Orthostatic Tachycardia syndrome in or about October/November 2008.

18. Plaintiff, THERESA ELDREDGE used DARVOCET in the manner in which it was prescribed to her at or about the time she suffered cardiovascular injuries and arrhythmias, including but limited to, wide complex tachycardia, in or about October/November 2008.

19. Plaintiff, THERESA ELDREDGE was not aware of nor could have been aware of the fact that her injuries were related in any way to DARVOCET until October of 2010.

20. In order to treat her arrhythmia and life threatening cardiac condition, plaintiff, THERESA ELDREDGE, underwent painful medical treatments.

21. Plaintiff, THERESA ELDREDGE, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong cardiac monitoring, treatment and medications.

22. The injuries and damages sustained by Plaintiff, THERESA ELDREDGE, were caused by Defendants' drug DARVOCET.

23. Upon information and belief, Defendant XANODYNE PHARMACEUTCALS, INC., at all relevant times, was and is a corporation organized under the laws of the State of Delaware with its principal place of business located in the State of Kentucky, and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

24. Upon information and belief, and at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription management medication.

25. Upon information and belief, Defendant XANODYNE PHARMACEUTCALS, INC., is the holder of approved New Drug Application ("NDA") for DARVOCET.

26. Upon information and belief, Defendant PROBST DISTRIBUTION, INC. f/k/a QUALITEST PHARMACEUTICALS, INC., is a corporation organized under the laws of the State of Alabama with its principal place of business located at 130 Vintage

Drive, Huntsville, Alabama, and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

27. Upon information and belief, Defendant VINTAGE PHARMACEUTICALS, LLC is a Limited Liability Company organized under the laws of the State of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama, and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

28. Upon information and belief, Defendant GENERICS BIDCO I, LLC, d/b/a QUALITEST PHARMACEUTICALS is a Limited Liability Company organized under the laws of the State of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama, and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

29. Upon information and belief, Defendant COVIDIEN, INC. is a corporation organized under the law of Delaware with a principal place of business located at 15 Hampshire Street, Mansfield, Massachusetts , and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

30. Upon information and belief, Defendant COVIDIEN, PLC is a corporation organized under the law of Ireland with a principal place of business located at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland , and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

31. Upon information and belief, Defendant MALLINCKRODT, INC. is a corporation organized under the law of New York with a principal place of business located at 675 McDonnell Blvd., Hazelwood, Missouri and is a wholly owned

subsidiary of COVIDIEN, PLC, and does business in the City and County of Philadelphia and the Commonwealth of Pennsylvania.

32. Upon information and belief, at all relevant times, the Defendants have transacted and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from interstate commerce.

33. Upon information and belief Defendants expected or should have expected that their acts would have consequences within the United States of America, and Langhorne Pennsylvania and within the confines of the Eastern District of Pennsylvania in particular and derived substantial revenue from interstate commerce, including commerce conducted within the Commonwealth of Pennsylvania.

34. Upon information and belief, and at all relevant times Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription management medication.

35. At all relevant times, Defendants or their predecessors in interest were and remain in the business of and did design, research, manufacture, test, advertise, promote, market, sell distribute, and/or DARVOCET for use as a prescription pain management medication.

36. DARVOCET has been used and referred to, at all relevant times, as the so-called "reference listed drug" (or "RLD") in abbreviated NDAs (ANDAs) for generic versions of the drug, submitted under the provisions of subsection (j) of FDCA §505, 21 USC §355, and added to that section by Section 101 of the so-called Hatch-Waxman Amendments (P.L. 98-417, 98 Stat. 1585) enacted on September 24,1984.

37. An applicant who submits an NDA per the provisions and procedures established under FDCA §505, 21 USC §355, is required to fully, truthfully and accurately disclose to the FDA, with its application, and periodically and at other times thereafter, data and information regarding the drug's chemistry, pharmacology, and other matters, including its proposed labeling. The FDA, as a condition for approval of the NDA, must be satisfied that the proposed labeling includes data and information about risks and side effects, test results for the drug, results of animal studies, results of clinical studies, and the drug's bioavailability, and other matters, adequate to enable physicians or other like foreseeable prescribers to use the drug safely.

38. Federal law requires one who owns or holds an FDA-approved NDA or ANDA to ensure at all times that the drug's labeling is and remains accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to perodically and at other times report to the FDA data related to the safety of the drug and/or to the accuracy of the labeling.

39. As holders of Abbreviated New Drug Applications (“ANDAs”) for generic versions of the DARVOCET, the Defendants are and have been required by federal law to ensure continuously that the labeling for their propoxyphene products contained accurate information that would constitute adequate warnings, for any doctors who would read the labeling, about the drug's intended uses, including actual uses other than the drug's "indications" to the extent the ANDA applicant would have knowledge or notice of such uses; to conduct post market safety surveillance; and to review all adverse drug event information (ADE reports).

40. Defendants were required by federal law to report in the DARVOCET

product labeling significant information discovered in the course of the fulfillment of its obligations as holders of ANDAs for generic versions of a drug, as outlined above, bearing on the risk and/or prevalence of side effects caused by the drug.

41. On information and belief, at all times relevant, Defendants affirmatively decided not to engage in active investigation of the risks of DARVOCET notwithstanding their ongoing obligations to ensure that the drug's labeling remained accurate and adequate.

42. About 10 million people in the U.S. received prescriptions for DARVOCET and other propoxyphene related drugs, in 2009 according to the FDA.

43. Upon information and belief, ADE data maintained by the FDA documents substantial numbers of serious adverse events associated with the use of Darvocet, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

44. In 2005, health authorities in Great Britain called for a phased withdrawal of propoxyphene containing products in that nation because of concerns about the drug's cardiotoxic effects.

45. In June 2009, the European Medicines Agency (EMEA) recommended that the marketing authorizations for propoxyphene be withdrawn across the European Union for safety concerns associated with cardiotoxicity.

46. Defendants ignored the correlation between the use of DARVOCET and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

47. Each of the Defendants breached its duty to provide adequate warnings

to the medical community, Plaintiff's physicians, Plaintiffs, and/or other foreseeable DARVOCET users similarly situated, in that they failed to:

i) ensure that DARVOCET warnings to the FDA, medical community, physicians, and Plaintiffs' physician were accurate and adequate, despite having extensive knowledge of the risks associated with the drug.

ii) conduct post market safety surveillance and report that information to the FDA, medical community, Plaintiffs' physicians, Plaintiffs and other like foreseeable users.

iii) review all adverse drug event information (ADE), and to report information bearing significantly upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by DARVOCET to the medical community, Plaintiff's physicians, Plaintiffs and other like foreseeable users.

iv) periodically review all medical literature regarding DARVOCET and report to the FDAand the medical community significant data concerning the efficacy or safety of the drug.

v) independently monitor their sales of DARVOCET and other propoxyphene products, and the medical literature, which would have alerted them to the fact that propoxyphene products were widely over prescribed, owing to the inadequate warnings provided to doctors.

48. Because of the misleading information that Defendants disseminated to physicians, and because of the failure of the Defendants generally to adequately inform the FDA, physicians and the medical community about the true risks associated with the use of DARVOCET, Plaintiff's physicians did not know or appreciate fully the risks of side effects associated with the use of the drug.

49. Despite mounting evidence that use of DARVOCET was associated with serious and potentially fatal heart arrhythmias, Defendants failed and refused to perform studies designed to accurately assess the cardiac risks of DARVOCET use.

50. In July 2009, Xanodyne Pharmaceuticals, which held the rights to the NDA for Darvon, the original Propoxyphene formulation on which the Defendants'

product DARVOCET is modeled, was ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of propoxyphene on the heart.

51. The results of the study ordered by the FDA indicated that even when taken at recommended doses, propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), increase the risk for serious abnormal heart rhythms which are linked to serious adverse effects, including sudden death.

52. On November 19, 2010, the FDA announced that Xanodyne Pharmaceuticals, had agreed to halt all U.S. Marketing of Darvon because of the potential of the drug to cause serious and potentially fatal heart arrhythmias, while being of very limited efficacy as a pain medication.

53. Also in November 2010 FDA requested that manufacturers and distributors of generic propoxyphene formulations, including the Defendants in this case voluntarily suspend marketing such products, including DARVOCET. It was only after FDA requested that the Defendants stop marketing the drug that Defendants ceased manufacturing and distributing DARVOCET.

54. The use of DARVOCET creates unique and dangerous risks compared to other prescription pain management medications. These risks include, inter alia heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

55. The Defendants did not provide adequate warnings to the FDA doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been reported by the medical

community.

56. By reason of the foregoing, Plaintiff has developed and/or is at extremely high risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Plaintiff has incurred and will in the future incur medical exprenses for the treatment of her injuries.

57. Plaintiff has endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

58. By reason of the foregoing, Plaintiff has been severely and permanently injured, and faces an increased risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' drug DARVOCET.

59. Defendants had an obligation to comply with the law in the manufacture, design, and sale of DARVOCET.

60. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* and the regulations promulgated thereunder, rendering their DARVOCET product adulterated and misbranded.

61. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants negligent *per se.*

COUNT I - STRICT LIABILITY - FAILURE-TO-WARN

62. Plaintiff hereby incorporatess by reference all preceding paragraphs as if fully set forth herein.

63. Each of the Defendants is liable under the common law and/or Product Liability Acts for personal injuries sustained by the plaintiff as a proximate result of its innocent, negligent and/or willful failure to give adequate warnings to physicians (or to their patients) bearing on the expected, intended, and/or common and foreseeable uses of the propoxyphene product or products that it made or sold and which the plaintiff came to ingest, as prescribed by her physicians and properly dispensed to her by their pharmacies.

64. As manufacturers of pharmaceutical products, specifically DARVOCET and/or other propoxyphene formulations, each of the Defendants is deemed to have possessed the knowledge of an expert in the uses of such products and the effects of such uses, including dangerous and and potentially dangerous side effects of such use.

65. Neither the plaintiff nor her physicians were in the possession of the knowledge about propoxyphene effects that Defendants, as manufacturers of the drug, actually possessed or are deemed to possess, concerning the risks of personal injury

associated the use of the drug, and none of them were given adequate warnings pertaining to such use.

66. The Defendants had a continuing duty, as information regarding the risks and dangers associated with the ordinary and foreseeable use of DARVOCET and/or propoxyphene products came to them, to exercise reasonable care to communicate to the FDA, consumers, including Plaintiff, or to her physicians, adequate warnings about those risks and dangers.

67. The Defendants distributed, marketed, promoted, and/or sold an unreasonably dangerous and defective product, namely the prescription drug known as DARVOCET and/or propoxyphene formulations, without adequate warnings and other clinically relevant information and data to the FDA, consumers, including Plaintiff, or to her physician or other health care providers empowered to prescribe and dispense DARVOCET and/or propoxyphene formulations. Through omission and affirmative misstatements, defendants severally and collectively misled the medical community about the risk and benefit balance of DARVOCET and/or propoxyphene formulations.

68. Despite the fact that the Defendants knew or should have known that DARVOCET and/or propoxyphene formulations caused unreasonable and dangerous side effects, they continued to manufacturer, sell, and distribute their propoxyphene formulations without communicating to the FDA, consumers, or to her physician or other health care providers, adequate clinically relevant information and data or that there existed safer and more or equally effective alternative drug products.

69. The Defendants knew or should have known that a class of consumers, which include the Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of their several and collective failure to provide adequate warnings.

70. The Defendants failed to provide timely and adequate warnings to the FDA, consumers, including Plaintiff, or to her physicians, in the following ways:

i) Defendants, failed to disseminate to doctors or to their patients adequate warnings or adequate clinically relevant information and data that would alert them to the dangerous risks of DARVOCET and/or propoxyphene formulations including, among other things serious arrhythmias;

ii) After they knew or should have known of the significant risks of, among other things, cardiotoxic effects, the Defendants failed to provide adequate postmarketing warnings and instructions;

iii) The Defendants, as manufacturers and distributors and sellers of propoxyphene formulations, owed to the Plaintiff, and other patients, a duty to communicate to them, the FDA or to physicians adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to propoxyphene formulations, and/or that there existed safer and more or equally effective alternative drug products.

71. By failing to give to Plaintiff or to her physicians adequate clinically relevant information and data and the FDA warnings regarding the adverse health risks associated with the ordinary, expected, and/or intended use of the propoxyphene formulations it manufactured, distributed, and/or sold, including the information that there existed safer and more or equally effective alternative non-propoxyphene drug products, each of the Defendants breached its duty the FDA, to purchasers and consumers of its propoxyphene formulations.

72. The actions of each of the Defendants, as described above, were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

73. Actions of each of the Defendants, as described above, also violated the state and federal statutes, including the FDCA, pertaining to the labeling of drugs and so rendered the propoxyphene product or products sold by that defendant "misbranded," as that term is used in those statutes.

74. As a direct and proximate result of the actions and inactions of the Defendants, as set forth above, Plaintiff was exposed to DARVOCET and/or propoxyphene formulations and suffered and continue to suffer the injuries and damages described in this Complaint.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT II - STRICT LIABILITY - DESIGN DEFECT

75. Plaintiff hereby incorporatess by reference all preceding paragraphs as if fully set forth herein.

76. The Defendants are liable to Plaintiff for the injuries and damages sustained by Plaintiff pursuant to state common law and/or state Product Liability Acts due to the defective design and/or formulation of their several products, namely DARVOCET and/or generic propoxyphene formulations.

77. At times material to these allegations, the Defendants manufactured, distributed, and/or sold one or more propoxyphene formulations.

78. The Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and as manufacturers of propoxyphene products, to the level of knowledge of an expert in the field of propoxyphene uses and effects, including side effects.

79. The DARVOCET and/or propoxyphene formulations prescribed for, dispensed to, and administered to or ingested by Plaintiff was defective in design or formulation in the following respects:

i) When it left the hands of the Defendant that manufactured and/or sold it, the propoxyphene formulations product was unreasonably dangerous to the extent beyond that which would reasonably be contemplated by Plaintiff or her physician;

ii) Any benefit of this product was outweighed by the serious and undisclosed risks of its use when used, per doctors' prescriptions, as the Defendants intended;

iii) The dosages and/or formulation of the propoxyphene formulations manufactured and/or sold by the Defendants were unreasonably dangerous;

iv) There are no patients for whom the benefits of DARVOCET and/or generic propoxyphene formulations outweighed the risks; and/or

v) There are no patients for whom DARVOCET and/or generic propoxyphene formulations is a safer and more efficacious drug than other drug products in the same class.

80. The DARVOCET and/or generic propoxyphene formulations dispensed to and administered to or ingested by Plaintiff were defective at the time they were distributed by or left the control of the Defendants that manufactured and/or sold them.

81. The DARVOCET and/or generic propoxyphene formulations manufactured and/or sold by the Defendants were expected to and did reach patients for whom they were prescribed, including Plaintiff, without substantial change in their condition.

82. The DARVOCET and/or generic propoxyphene formulations manufactured and/or sold by the Defendants were administered to or ingested by Plaintiff without substantial change in their condition.

83. Plaintiff was a patient for whom the products manufactured and/or sold by the Defendants reasonably expected DARVOCET or propoxyphene formulations to be prescribed, and would be expected to ingest or otherwise receive administration of their propoxyphene formulations.

84. Each of the Defendants was entitled to withdraw its propoxyphene formulations product from the market at any time, but failed to do so in a timely and responsible manner.

85. The defects in the DARVOCET and/or other propoxyphene formulations ingested by or administered to Plaintiff were a direct and proximate cause of the injuryand damage sustained by Plaintiff as set forth in this Complaint.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT III – NEGLIGENCE

86. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

87. Pursuant to common law and/or the Product Liability Act, and due to its negligent development, study, manufacture, distribution and sale of DARVOCET and/or generic propoxyphene formulations, each of the Defendants is liable to Plaintiff who consumed its propoxyphene product or products for injuries caused by those products.

88. At all times relevant to this lawsuit, each of the Defendants owed a duty to the FDA and consumers, like Plaintiff, to assess, manage, and communicate the risks, dangers, and adverse effects of DARVOCET and/or propoxyphene formulations and to suspend distribution and sale of its DARVOCET and/or propoxyphene formulations when it discovered the drug to be umeasonably dangerous.

89. Defendants' duties included, but were not limited to,carefully and properly designing, testing, studying, manufacturing, promoting, selling, and/or distributing its DARVOCET and/or propoxyphene products into the stream of commerce as a reasonably safe prescription drug product.

90. Defendants' duties further included, but were not limited to, distributing their respective DARVOCET and/or propoxyphene formulations with adequate information provided to the FDA, consumers and/or physicians regarding the appropriate use of the drug product.

91. Each of the Defendants negligently and carelessly breached the above-described duties to Plaintiff by committing negligent acts and/or omissions including, but not limited to, the following:

i) They failed to use ordinary care in designing, testing, and manufacturing, a product which would be reasonably safe to use without appropriate labeling, marketing, aud/or the provision of adequate information to the FDA, consumers or doctors;

ii) They failed to use ordinary care in marketing, labeling, and communicating adequate warnings about their respective products to consumers and/or her physician so as to reveal and communicate the high risk to users of unreasonable, dangerous side-effects, such as heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, when compared to the use of alternative drugs in the same class or compared to the use of no drugs;

iii) They failed to exercise ordinary care to communicate, to consumers or to doctors, adequate information that would alert doctors or consumers to the potential adverse side effects associated with the use of their respective DARVOCET and/or propoxyphene formulations and the nature, severity and duration of such adverse effects, either compared to the use of alternative drugs in the same class or compared to the use of no drugs;

iv) They failed to exercise ordinary care either to conduct or in conducting post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses adequate to determine the safety profile and side effects of their respective DARVOCET and/or propoxyphene formulations, either compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy;

v) They failed to exercise ordinary care to communicate to the FDA, Plaintiff or to her physicians, either directly or indirectly, orally or in writing, adequate warnings about the true risk of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, injury and death as a result of the use of their respective DARVOCET and/or propoxyphene formulations, either compared to the use of alternative drugs in the same class or compared to the use of non-drug therapy;

vi) They failed to exercise ordinary care to protect users of their respecive DARVOCET and/or propoxyphene formulations from an unreasonable risk of injury due to the ordinary, expected, or common uses of DARVOCET and/or generic propoxyphene formulations, in the face of continued or past efforts to promote to physicians the safety and effectiveness of the drug, while downplaying its risks, after they knew or should have known that those efforts overstated the safety and downplayed the risks of the drug compared to the use of alternative drugs in the same class or compared to the use of nondrug therapy;

vii) They failed to communicate to Plaintiff or to her physician information that longterm use of the DARVOCET and/or generic propoxyphene formulations involved a higher risk of involuntaty movements and/or was unreasonably dangerous than was commonly appreciated in the medical community or as compared to the use of alternative drugs in the same class or to the use of non-drug therapy, after they knew or should have known that to be the case.

viii) Owing to a failure to exercise due care, they failed to obtain, at the time of Plaintiff' ingestion, scientific data that would indicate the true association between the use of DARVOCET and/or propoxyphene formulations and the risk of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, either compared to the use of alternative drugs or compared to the use of non-drug therapy, even though they could legally have distributed the information they had or should have had to the FDA, physicians or their patients, regardless of whether the FDA had approved that information previously for inclusion in the drug's labeling;

ix) They failed to communicate to physicians, or to consumers, like Plaintiff, scientific data which indicated that DARVOCET and/or propoxyphene formulations was unreasonably dangerous, either compared to the use of alternative drngs in the same class or compared to the use of non-drug therapy, and that there were no patients or only very few patients in whom the benefits of their respective products outweighed the risks;

x) They failed to promptly withdraw their respective DARVOCET and/or propoxyphene formulations from the market and were otherwise careless or negligent.

92. The Defendants continued to manufacture and distribute their respective versions of the drug when they knew or should have known that propoxyphene formulations caused unreasonably dangerous side effects, which many users of their propoxyphene formulations would be unable to remedy by any means, and that there were safer and less expensive alternatives available.

93. Defendants, as manufacturers of brand name or generic versions of the drug, are by law deemed to possess the knowledge of an expert in the uses and effects of the drug, and as such should have known that consumers, like Plaintiff, would suffer injury as a result of ingesting their respective propoxyphene formulations as prescribed by their physicians and properly dispensed by their pharmacies.

94. As a direct and proximate cause of Defendants' negligent acts and/or omissions, Plaintiff suffered injuries and damages, as set forth in this Complaint.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT IV - NEGLIGENCE *PER SE*

95. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

96. Under the doctrine of negligence *per se*, the duty of the Defendants to exercise reasonable care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers associated with the use of their respective DARVOCET and propoxyphene products, included the obligation to conform their products and activities related to those products to safety standards imposed by applicable statutes or regulations.

97. Distribution by the Defendants of their respective propoxyphene formulations, specifically their acts and omissions as described above, constitutes violations of FDCA §301(a), 21 USC §331(a), which declares unlawful the distribution of a drug that is "misbranded," as that term is defined by standards established in FDCA §502, 21 USC §352, and in regulations duly promulgated to clarify those standards, and also a violation of parallel state statutes and regulations. Conduct in violation of these statutes and regulations constitutes a breach of duty of reasonable care toward the plaintiffs that would subject the defendants to civil liability for personal injuries proximately caused by the violations.

98. As lawful consumers of DARVOCET and/or propoxyphene formulations distributed by the several Defendants, Plaintiff is within the class of persons the statutes and regulations described above are designed to protect, and Plaintiff' inujuries are the type of harm these statutes and regulations are intended to prevent.

99. As a direct and proximate cause of the violations of these statutes and regulations by the Defendants, which therefore constitute negligent acts and/or omissions, Plaintiff suffered injuries and damages, as set forth in this Complaint.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT V - CONSTRUCTIVE FRAUD

100. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

101. At the time DARVOCET and/or generic propoxyphene formulations were manufactured, distributed, and sold to Plaintiff, the defendants were in a unique position of knowledge, which was not possessed by Plaintiff or her physician, concerning the safety and effectiveness of DARVOCET, and thereby held a position of superiority over Plaintiff.

102. Through their unique knowledge and expertise regarding the defective nature of DARVOCET and generic propoxyphene formulations, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff's physicians that they were

in possession of facts demonstrating that DARVOCET and generic propoxyphene formulations were safe and effective for their intended use and were not defective.

103. Defendants' representations to Plaintiff's physicians were made to induce the purchase of DARVOCET and/or propoxyphene formulations, and Plaintiff and her physician relied upon those statements when purchasing and administering DARVOCET and/or propoxyphene formulations.

104. Plaintiff and her physician reasonably relied on these misrepresentations.

105. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and her physician and engaged in constructive fraud in their relationship.

106. As a direct and proximate result of constructive fraud, as perpetrated by defendant Wyeth, and knowingly assented to and passively cooperated in by the other Defendants, Plaintiff has suffered injuries and damage, as set forth in this Complaint.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT VI - BREACH OF EXPRESS WARRANTY

107. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

108. Defendants expressly warranted that DARVOCET was safe and effective when used as directed.

109. The prescription pain management medication DARVOCET does not

conform to these express representations because DARVOCET is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss as more fully set forth herein.

110. Plaintiff did rely on the express warranties of the Defendants herein.

111. Members of the medical community, including Plaintiff's physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of DARVOCET as prescription pain medication in recommending, prescribing, and/or dispensing DARVOCET.

112. The Defendants herein breached the aforesaid express warranties, as their drug DARVOCET was defective.

113. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that DARVOCET was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other prescription pain management medications, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

114. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that DARVOCET was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

115. As a result of the foregoing acts and/or omissions the Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as past medical expenses and the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

116. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the potential of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants's drug DARVOCET.

117. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

118. By reason of the foregoing, Plaintiff has been directly and proximately damaged and seeks full and fair compensation.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT VII - BREACH OF IMPLIED WARRANTIES

119. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

120. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET, for use as a prescription pain management medication.

121. At the time Defendants marketed, sold, and distributed DARVOCET for use by Plaintiff, Defendants knew of the use for which DARVOCET was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

122. The Defendants impliedly represented and warranted to the users of DARVOCET and their physicians, healthcare providers, and/or the FDA that DARVOCET was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

123. That said representations and warranties aforementioned were false, misleading, and inaccurate in that DARVOCET was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

124. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

125. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether DARVOCET was of merchantable quality and safe and fit for its intended use.

126. The prescription pain management medication DARVOCET was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous

condition and the product and accompanying materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

127. The Defendants herein breached the aforesaid implied warranties, as its drug DARVOCET was not fit for its intended purposes and uses.

128. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as past medical expenses and the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

129. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

130. By reason of the foregoing, Plaintiff has been directly and proximately damaged and seeks full and fair compensation therefore.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT VIII - UNFAIR AND DECEPTIVE TRADE PRACTICES

131. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

132. State laws require the Defendants, as merchants, to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of their prescription drug products.

133. Defendants financed, assisted, supported and participated in advertising and other, similar efforts to promote the use of DARVOCET and/or propoxyphene formulations, in order to create demand for the drug and thereby increase sales and profits.

134. The Defendants, in the manner described, deliberately misrepresented the safety of DARVOCET and/or propoxyphene formulations and intentionally concealed the risks attendant to use of the drug. Through these misrepresentations, Defendants intended to influence (and did influence) the decisions of prescribing physicians and the drug-taking of their patients toward the end of increasing and maintaining the prescribing, purchasing, and use of DARVOCET and generic propoxyphene formulations, and excluding the options of not using a drug or using substantially cheaper and/or safer alternative drugs of the same class.

135. Defendants while engaged in the conduct and practices identified above committed one or more violations of state law, including, but not limited to, the following:

a.) They made false and misleading representations and omissions of material facts regarding DARVOCET and/or generic propoxyphene formulations;

b.) They concealed and otherwise failed to publicize the risk of injury associated with DARVOCET and/or generic propoxyphene formulations in order to promote sales of the drug and maximize profits; and

c.) They engaged in advertising and promotion of DARVOCET and/or propoxyphene formulations without conducting sufficient pre-clinical, clinical and post-approval testing and adequate post-marketing surveillance and analyses of the drug.

136. The Defendants thereby intended to and did affect the price of DARVOCET and and generic propoxyphene formulations, unfairly and deceptively maintained the price of DARVOCET and generic propoxyphene formulations at an inflated level not otherwise obtainable, and caused Plaintiff and the consuming public generally to pay more for these products than was warranted or then they would otherwise have paid in the absence of the misrepresentations and concealment.

137. The above-described conduct, practices, acts and omissions were immoral, oppressive, unethical and/or unscrupulous, in violation of the law, and/or offend public policy.

138. The above-described conduct, practices, acts and omissions caused consumers in general and Plaintiff in particular permanent and substantial financial loss, which loss could not reasonably have been avoided, and which was not outweighed by any countervailing benefit to the consuming public. Consumers in general, Plaintiff in particular, incurred unnecessary expenses for a product that was purchased only because of the unfair, unscrupulous, oppressive and/or deceptive acts or practices of the Defendants.

139. As a consequence of this wrongful conduct, by Defendants, Plaintiff suffered an ascertainable financial loss: the difference between the price paid for DARVOCET and/or propoxyphene formulations as a result of these unfair trade practices and the cost of any of the substantially cheaper, and safer, drug alternative.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT IX - UNJUST ENRICHMENT

140. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

141. As the intended and expected result of the conscious wrongdoing of Defendants, each of the defendants have profited and benefited from the purchase and use of DARVOCET or propoxyphene formulations by Plaintiff.

142. Defendants have voluntarily accepted and retained these profits and benefits derived from Plaintiff with full knowledge and awareness that, as a result, Plaintiff and other consumers were not receiving products of the quality, nature or fitness that had been represented by their manufacturers and sellers, or that Plaintiff, as reasonable consumers, expected to receive.

143. By virtue of the conscious wrongdoing alleged above, the Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity and hereby seeks the disgorgement and restitution of the profits, revenues and benefits Defendants obtained through the wrongdoing, to the extent and in the amount deemed

appropriate by the Court; and such other relief as the Court deems just and proper to remedy the unjust enrichment of Defendants.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

COUNT X - NEGLIGENT MISREPRESENTATION

144. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

145. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, DARVOCET, had been tested and found to be safe and effective for prescription pain management.

146. The representations made by Defendants were, in fact, false.

147. Defendants failed to exercise ordinary care in the representation of DARVOCET, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented DARVOCET's high risk of unreasonable, dangerous side effects.

148. Defendants breached their duty in representing DARVOCET's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

149. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that

DARVOCET had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as past medical expenses and the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

150. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

151. By reason of the foregoing, Plaintiff has been directly and proximately damaged and seeks full and fair compensation therefore.

WHEREFORE, Plaintiff claims damages, both compensatory and punitive against all Defendants, as well as all other damages, attorneys fees and costs permitted to be recovered under the law.

JURY CLAIM

Plaintiff claims a trial by jury on all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court grant them the following relief against Defendants, jointly and severally, on all counts of this Complaint, including:

a) Money Damages representing fair, just and reasonable compensation for her common law and statutory claims;

b) Punitive and/or Treble Damages pursuant to state law;

c) Disgorgement of profits and restitution of all costs;

d) Attorneys' fees pursuant to state law;

e) Pre-judgment and post -judgment interest as authorized by law on the judgments which enter on Plaintiff' behalf;

f) Costs of suit; and

g) Such other relief as is deemed just and appropriate.

Respectfully submitted,

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Date: March 11, 2011